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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,811	06/29/2001	Thomas D. Madden	16303-008020	7024
500	7590	04/28/2004	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			OSTRUP, CLINTON T	
701 FIFTH AVE				
SUITE 6300			ART UNIT	
SEATTLE, WA 98104-7092			PAPER NUMBER	
			1614	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,811

Applicant(s)

MADDEN ET AL.

Examiner

Clinton Ostrup

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,13-15,17 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-5, and 17 is/are rejected.
- 7) ☒ Claim(s) 13-15,17 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-2, 4-5, 13-15, 17 and 26 are pending in this application.

Priority

Priority to U.S. Provisional Application Numbers 60/264,616, filed January 26, 2001, and 60/215,556 filed June 30, 2000 has been acknowledged.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Applicant has indicated claims 6-12 and claims 18-25 as being cancelled and then has the status of claims 7 and 12 as "(Original)" and the status of claims 8, 9, and 11 as "(Previously Presented)." For the purpose of examination the examiner has considered claims 6-12 as being cancelled because page 2, last line; page 5, line 3; page 6, line 9; page 9, lines 20-21; and page 10, lines 1-2 either expressly or implicitly describe these claims as being cancelled. Moreover, once a claim has been canceled the same claim number cannot be presented again in the same application. Moreover, claims 18-25 have been considered as cancelled since the status identifier for claims 18-25 describes them as being cancelled.

Finally, claims 7-9, 11-15, 17, and 26 are objected to because the claim set currently presented does not match the claim set previously presented. For example,

claims 7-9 (in the response filed February 19, 2004) appear to correspond to claims 13-15 (in the response filed October 7, 2003). Likewise, claims 11-15 (in the response filed February 19, 2004) appear to correspond to claims 17-21 (in the response filed October 7, 2003) and claim 17 (in the response filed February 19, 2004) appears to correspond to claim 23 (in the response filed October 7, 2003).

Claim 26 is objected to as depending from a rejected base claim.

Appropriate correction is required.

Response to Applicant's Arguments/Amendment

Double Patenting

As indicated in the previous Office Action, Paper No. 16, mailed November 19, 2003, Applicants' request that the Obviousness-Type Double Patenting rejection be held in abeyance has previously been noted, however, all reasonable rejections are made. Applicants may hold their response to this rejection in abeyance until allowable subject matter has been indicated; however, the said rejection has been MAINTAINED for the reasons indicated in Paper No. 5, mailed July 22, 2002; Paper No. 9, mailed April 7, 2003; and Paper No. 16, mailed November 19, 2003, as well as those found below.

In regard to Applicants' inquiry as to why there is a discrepancy between the claims rejected in "the maintained rejection and those subject to the new rejection," the Examiner respectfully reminds Applicants that once a claim is cancelled it is no longer pending in the application and therefore no longer subject to the rejection. As for claim 23, applicants' amendment necessitated the inclusion of this claim in the double

patenting rejection. Since Applicants' claim 17 (in the response filed February 19, 2004) corresponds to claim 23 (in the response filed October 7, 2003) this rejection is hereby applied to claim 17, as it was to claim 23 in Paper No. 16.

Thus, claims 1-2 and 4-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-35, 37, 39-57, and 60-63 of copending Application No. 09/896,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to liposomal formulations comprising camptothecin and/or topotecan compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

Applicant's cancellation of claims 6-7 has made the rejection of claims 6-7 under 35 U.S.C. 102(b) as being anticipated by Madden et al., Encapsulation of Topotecan in Lipid-Based Carrier Systems. Evaluation of Drug Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L12210 and B16, Proc. Of ASCO, 17: abstract #754 (1998), moot. Therefore, the said rejection has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments and amendment filed February 19, 2004, to the rejection of claims 1-2, 4-5, and 23 under 35 U.S.C. 103(a) as being unpatentable over Madden et al., Encapsulation of Topotecan in Lipid-Based Carrier Systems. Evaluation of Drug

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Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L12210 and B16, Proc. Of ASCO, 17; abstract #754 (1998)

have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's arguments and amendment filed February 19, 2004, to the rejection of claims 1, 2, 4-5, 13-15, 17 and 26 under 35 U.S.C. 103(a) as being unpatentable over Madden et al., Encapsulation of Topotecan in Lipid-Based Carrier Systems. Evaluation of Drug Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L12210 and B16, Proc. Of ASCO, 17; abstract #754 (1998) and further in view of Ormrod et al., Topotecan: A review of its Efficacy in Small Cell Lung Cancer, Adis Drug Evaluation, Drugs 1999; Sep; 58(3); pages 533-551 have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's cancellation of claims 8 and 10-11 has made the rejection of claims 8 and 10-11 under 35 U.S.C. 103(a) as being unpatentable over Madden et al., Encapsulation of Topotecan in Lipid-Based Carrier Systems. Evaluation of Drug Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L12210 and B16, Proc. Of ASCO, 17; abstract #754 (1998) and further in view of Slater et al., 6,355,268, moot. Therefore, the said rejection has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-0582. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Clinton Ostrup
Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

